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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,030	12/12/2003	Vahid C. Saadat	USGINZ02513	3503
40518 7590 03/27/2009 LEVINE BAGADE HAN LLP 2483 EAST BAYSHORE ROAD, SUITE 100 PALO ALTO, CA 94303				
EXAMINER				
LANG, AMY T				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/735,030

Applicant(s)

SAADAT ET AL.

Examiner

AMY T. LANG

Art Unit

3731

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-29, 32-35 and 40-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-29, 32-35, and 40-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the overtube including at least one steering wire that provides a steering capability for a distal region of the overtube must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Claims 26-29, 32-35, and 40-44** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 26 recites a mechanism that transitions the overtube between a flexible and rigid state. As discussed in the instant specification, tension wires (1016) provide this mechanism (see paragraphs [0232]; [0234]). However, claim 26 also recites a steering wire for steering the distal end of the overtube. The instant specification also teaches the steering wire as a tensioning wire (see paragraph [0247]). Therefore, it appears as though the instant specification does not provide support for both a mechanism and a separate steering wire since both components comprise the disclosed tensioning wires. Therefore, the instant specification supports either the mechanism or the steering wire, but not both. Claims 26-29, 32-35, and 40-44 are dependent on claim 26 and therefore are also not supported by the instant specification.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. **Claims 26-29, 32-35, and 40-49** are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (US 2002/0111534 A1) in view of Jaffe (US 2002/0161281 A1).

With regard to **claims 26 and 45**, Suzuki et al. (hereinafter Suzuki) discloses an apparatus for performing a medical procedure within a hollow body organ (see entire document). The device comprises an overtube (84) and a first catheter (14) inserted through the overtube (Figures 1 and 3; [0038]; [0039]). It is the examiner's position that a user is able to manually steer the distal end of the overtube so that the overtube comprises a steerable distal region. As shown in Figures 1 and 12, the first catheter comprises a flexible tube and a distal tissue engaging assembly with jaws (17a, 17b)

((0039)). The tissue engaging assembly grabs a patient's tissue to form a first tissue contact point (Figure 13).

Suzuki further discloses a flexible delivery catheter (42) comprising an internal lumen through which a needle (44) is inserted ([0044]; Figure 8). Initially, the flexible delivery catheter is inserted into the patient parallel to the first catheter, a direction that is aligned with a longitudinal axis of the proximal portion of the flexible delivery catheter ([0054]). A distal portion of the flexible delivery catheter is then bent toward the first tissue contact point ([0054]; Figure 17). It is the examiner's position that the bending produces a bent catheter that is generally transverse to the longitudinal axis of the proximal portion of the catheter. The needle is then slidably extended out of the distal end of the flexible delivery catheter and through the tissue ([0055]; Figure 17). Therefore, the needle, which was previously retained within bending section, now extends from a distal end of the bending section of the flexible delivery catheter.

If applicant were to argue that the bending of the flexible delivery catheter does not produce a bend that is generally transverse to the longitudinal axis, is the examiner position that the delivery catheter of Suzuki is adapted to bend substantially ninety degrees. This would allow the needle to produce a clean cut while traversing through the tissue.

Once the needle is deployed through the tissue, as shown in Figure 17, a suture (46) on suture retaining device (50) is utilized to secure a tissue fold produced at the first tissue contact point ([0058]). Therefore, the flexible delivery catheter and suture

retaining device work together to deliver an anchor, suture (36), and secure a tissue fold and therefore together overlap the instantly claimed anchor delivery assembly.

However, Suzuki does not specifically disclose the guide tube as having a flexible state and a rigid state and a steering wire that provides a steering capability to the distal region of the overtube.

Jaffe discloses an overtube, guide tube (14), designed to facilitate insertion of an endoscope through a tortuous pathway ([0002]). The guide tube is slideably disposed over the catheter and comprises a flexible and rigid state (Figure 1; [0028]; [0037]; [0038]). As shown in Figure 3, tensioning elements (30) transition the overtube between the flexible and rigid states ([0041]). Therefore, tensioning elements (30) clearly overlap the instantly claimed mechanism. It is the examiner's position that the tensioning elements are configured to be manipulated from outside a patient's body. Since the overtube of Jaffe advantageously facilitates insertion of an endoscope through an internal passageway, it would have been obvious to one of ordinary skill at the time of the invention for Suzuki to utilize the overtube of Jaffe.

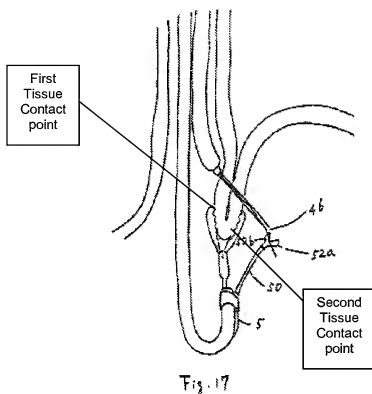
Additionally, Jaffe teaches the distal end of the guide tube can be controlled through a steering capability to provide an optimal pathway through the patient ([0044]). Tensioning elements (30) are also disclosed as steering the distal end of the overtube by causing it to "flex into different position" ([0044]) and therefore overlap the instantly claimed steering wires. Since Jaffe teaches multiple tensioning elements (30A, 30B, 30C, and 30D), it is the examiner's position that, for instance, tensioning elements 30A

and 30B overlap the instantly claimed steering wires and tensioning elements 30C and 30D overlap the instantly claimed mechanism to transition the overtube.

With regard to **claims 27-29**, Jaffe teaches wherein tensioning elements (30) are placed circumferentially about the overtube to control the transition from a flexible to rigid state or vice versa. The tensioning elements may be manipulated individually, so that only one portion of the overtube is transitioned ([0041]). For instance, as shown in Figure 3 of Jaffe, when only tensioning element 30C is manipulated, only that side of the overtube would transition from a flexible to a rigid state or vice versa. The side of the overtube that tensioning element 30D runs would not transition, so that only one section of the overtube remains in a flexible or rigid state while another section is manipulated and transitioned to the opposite state.

With regard to **claim 32**, as shown in Figure 17 of Suzuki, the needle contacts the tissue at a location proximal of the first tissue contact point.

With regard to **claim 33**, it is also the examiner's position that each jaw member (17a, 17b) of Suzuki touches the tissue to form a first and second tissue contact point. As shown in Figure 17, the first tissue contact point is proximal of the second tissue contact point. Slider handle (23) manipulates the jaw members and therefore overlaps the instantly claimed tissue approximation device.



With regard to **claims 34 and 35**, Suzuki merely discloses two catheters inserted within an overtube (Figure 1). Therefore, it is the examiner's position that it would have been obvious at the time of the invention to flip the device so that the first catheter lies above the flexible delivery catheter. This entry angle would be advantageous while attempting to access various anatomical parts. Therefore, the tissue grabbing assembly would contact the tissue to form first and third contact points. The needle would produce a second tissue contact point and the first tissue contact point would be proximal of the third tissue contact point. Additionally, all three tissue contact points would be linearly displaced.

With regard to **claims 41-44**, the apparatus disclosed by Suzuki in view of Jaffe is configured to engage mucosa, muscularis, or serosa.

With regard to **claims 46 and 49**, the anchor, suture (46) is configured to be delivered through the needle (44) since the suture is inserted in the needle ([0058]).

With regard to **claims 40, 47, and 48**, Suzuki further discloses endoscope (2 or 6) movably disposed within the overtube ([0038]).

Response to Arguments

7. Applicant's arguments with respect to claims 26-29, 32-35, and 40-49 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

03/24/2009
/Amy T Lang/
Examiner, Art Unit 3731

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Supervisory Patent Examiner, Art Unit 3731
3/25/09